

REMARKS

This is in response to the Office Action mailed April 8, 2003.

In that Office Action, Claims 1-10 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. According to the Examiner, Claim 1 is incomplete because it does not recite a synthetic medium container containing a medium.

Claims 1, 3-10 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,965,349 to Lin et al.

Claims 1, 3-10 were rejected under 35 USC §102(b) as being anticipated by International Publication No. WO 90/00059.

Claims 1, 2, 5-10 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,769,839 to Carmen et al.

By this Amendment, Claim 1 has been amended and is directed to a method for preparing a pathogen inactivation treatment-ready blood product that includes the steps of providing a container system comprising at least a pre-connected interim container and a container including a liquid synthetic medium wherein the medium container is in openable flow communication with the interim container. The method also includes providing a source container including a quantity of blood or blood

component separate from the container system and establishing fluid communication between the source container and the interim container. The method of Claim 1, as amended, further includes transferring blood or the blood component to the interim container and combining a selected quantity of the blood or the blood component with a selected quantity of the synthetic medium within said interim container to provide a pre-selected ratio of the blood or blood product to the synthetic medium that is effective for the pathogen inactivation treatment.

In view of the amendment to Claim 1, Applicants submit that the rejection under 35 USC §112, second paragraph, has been overcome by the recitation of a container "including a synthetic medium."

In addition, Applicants submit that by this Amendment, the subject matter of Claim 1 is neither anticipated nor would have been obvious in view of the references relied upon by the Office.

Turning first to Lin et al., that patent describes a method for preparing a blood platelet product intended for pathogen inactivation. However, Lin et al. discloses adding platelets directly to the container that includes a synthetic storage medium. In contrast, in the present invention, the blood or blood component is added to an interim container wherein it is combined with the synthetic liquid medium. Use of an interim

container, as recited in Claim 1, allows for the selective addition and/or removal of synthetic medium and/or other fluids to achieve the pre-selected ratio of blood or blood component to the synthetic media. This is described in greater detail in paragraphs [0055] and [0056] of the application.

Turning now to the rejection based on WO 90/00059, it is submitted that this reference neither shows nor suggests a method for preparing a pathogen inactivation treatment-ready blood product that includes, among other things, combining a selected quantity of blood or blood component with a selected quantity of a synthetic medium to provide a pre-selected ratio of the blood or blood product to the synthetic medium effective for pathogen inactivation. WO 90/00059 is generally directed to a procedure and container for the preparation and storage of platelet concentrates (and red blood cells). It describes a series of steps but does not describe or suggest a method where the desired blood or blood component is combined with a synthetic medium in a pre-selected ratio that is effective for pathogen inactivation treatment.

Similarly, the patent to Carmen et al. also discloses a method for preparing red cells using a specific container system with at least two containers, a so-called "interim" container and a synthetic medium container connected to each other. According to the Office, bag 106 "can" be termed the synthetic

medium container and bag 102 "can" be termed the source container. While Carmen et al. certainly discloses a multi-container blood component processing system, it does not describe the method recited in Claim 1, as amended. The hypothetical processing scenario proposed by the Office can only be arrived at through hindsight, and is not fairly suggested by the patent itself. As in the International Publication WO 90/00059, Carmen et al. does not disclose or suggest combining a blood or blood component in a pre-selected ratio effective for a pathogen inactivation treatment. For these reasons, none of the references relied upon by the Examiner anticipate or would have rendered obvious the method of Claim 1, as amended.

Applicants wish to call other amendments to the Examiner's attention. The term "openable" has been added to Claim 1 to recognize that the flow path between interim container and synthetic medium container may be initially or subsequently closed, but openable (as discussed, for example, in paragraph [0055]. Claims 1 and 7 have been amended to more positively call for "establishing" flow communication. Claims 9 and 10 have been amended to describe the removed solution in terms of its location ("supernatant") rather than its composition ("aqueous").

In addition to the amendments made to the pending claims, Applicants have also added new dependent Claims 25-28. These

claims further recite providing a container system including a third container for receiving supernatant from the interim container.

Applicants have also made two amendments to the specification. First, in paragraph [0043], Applicants have corrected a typographical error in the recitation of a preferred range for sodium phosphate in a synthetic platelet medium. The range set forth in the application was "22-5", which is clearly a typographical error. That range should have read 22-35. It is submitted that this correction does not expand the disclosure beyond what was originally filed, as the range of 22-35 for sodium phosphate is clearly within the broader range set forth in the previous paragraphs (e.g., paragraph [0042]), for sodium phosphate. Entry of this amendment is respectfully requested.

In addition, the reference to Fig. 4 in paragraph [0049] has been changed to correctly reference Fig. 5.

Finally, with this Amendment, Applicants submit a Second Supplemental Information Disclosure Statement citing recently issued U.S. Patent No. 6,544,727. That patent discusses (for example, in columns 67-68, 97 and 140) preparation of a platelet product intended for pathogen inactivation. Applicants request that this patent (and the references submitted in the April 16, 2003 Supplemental Information Disclosure Statement) be

considered in light of the claims, as amended, and made of record.

Reconsideration of the pending Claims 1-5, 7-10 and 25-28 is respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Andrew G. Kolomayets", written over a horizontal line.

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